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DOCKET No. 21371-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION

CHRISTINE MARKERT-HAHN, ET AL

SERIAL NO.: 10/647,720

FILED: August 25, 2003

FOR: IMPROVED METHOD OF BISULFITE

TREATMENT

EXAMINER: Unassigned

ART UNIT: Unassigned

INFORMATION DISCLOSURE STATEMENT

Mail Stop <u>Disclosure</u> Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicant submits herewith a Form-1449, in compliance with the duty of disclosure requirements of 37 C.F.R. §1.56 1.97 and 1.98, listing accompanying documents that may be considered material to the examination of this application. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits, whichever event occurs last. No certification or fee is therefore required under 37 C.F.R. § 1.97(b). However, should the Commissioner determine that fees are due in order for the Information Disclosure Statement to be considered at this stage, the Commissioner is hereby authorized to charge any fee deficiency, or credit any

overpayment, to Deposit Account No. 50-0812. A duplicate copy of this communication is enclosed.

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested.

Respectfully submitted,

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INFORMATION DISCLOSURE CITATION (Use Several sheets if necessary) NOV 1 4 2003					ATTY DOCKET NO. 1 21371-US		SERIAL NO. 10/647,720				
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U.S. PATENT						T DOCUMENTS					
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		DOCUMENT NUMBER		DATE		COUNTRY CLAS		SUBCLASS	TRANSLATION YES NO		
	28	wo	01/098528 A3	12/27/2001	PCT				120		
e	29	wo	01/37291 A1	05/25/2001	PCT			,			
-	30	wo	0 02/31186 A2	04/18/2002	PCT						
		-									
-	<u> </u>	1	OTHER DOCUME	NTS (Includin	g Author,	Title, Date, Pertinent I	Pages, Etc	:.)			
		31	Benyajati, C., et al., 1980, "Alcohol dehydrogenase in Drosophila: Isolation and characterization of messenger RNA and cDNA clone", <i>Nucleic Acids Research</i> , 8(23):5649-5667								
		32	Clark, S., 1994, "High sensitivty mapping of methylated cytosines", Nucleic Acids Research, 22(15):2990-2997								
EXAMINER				DATE CONSIDERED							
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.											

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Patent and Trademark Office * U.S. DEPARTMENT OF COMMERCE

Serial No. 10/647,720 Applicants: Markert-Hahn, et al. Form PTO-1449 Page 4 of 5

PADEMNAK	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)						
33	Feil, R., et al., 1994, "Methylation analysis on individual chromosomes: improved protocol for bisulphate genomic sequencing", <i>Nucleic Acids Research</i> , 22(4):695-696						
34	Fraga, M., et al., 2002, "DNA Methylation: A Profile of Methods and Applications", BioTechniques, 33(3)632649						
35	Frommer, M., et al., 1992, "A Genomic sequencing protocol that yields a positive display of 5-methylcytosine residues in individual DNA strands", <i>Proc. Natl. Acad. Sci. USA</i> , 89:1827-1831						
36	Goyon, C., et al, 1994, "Perpetuation of Sytosine Methylation in Asobolus immerses implies a Novel Type of Maintenance Methylase", J. Med. Biol., 240:42-51						
37	Grigg, G., 1996, "Sequencing 5- methylcytosine residues by bisulphate method", DNA Sequence, 6:189-198						
38	Grigg, G., et al., 1994, "Sequencing 5- methylcytosine residues in Genomic DNA", BioEssays, 16(6):431-436						
Grunau, C., et al., 2001, "Bisulfite genomic sequencing: systematic investigation of critical experimentary," Nucleic Acids Research, 29(13):e65-5							
40	Guatelli, J., et al., 1990, "Isothermal, in vitro amplification of nucleic acids by a multienzyme reaction modeled after retroviral replication", Proc. Natl., Acad, Sci. USA, 87:1874-1878						
41	Intergen Company, "CpGenome™ DNA Modification Kit", Catalog No. S7820						
42	Intergen Company, "Methylation Specific PCR" Literature						
43	Jakobi, R., et al., 1988, "Filter-Supported Preparation of λ Phage DNA", Analytical Biochemistry, 175:196-201						
44	Kwoh, D., et al., 1989, "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format", <i>Proc. Natl. Acad. Sci. USA</i> , 86:1173-1177						
45	Komlyama, M., et al., 1994, "Catalysis of Diethylenetriamine for Bisulfite-Induced Deamination of Cytosine in Oligodeoxyribonucleotides", <i>Tetrahedron Letters</i> , 35(44):8185-8188						
46	Marko, M., 1982, "A procedure for the large-scale isolation of Highly purified Plasmid DNA Using Alkaline Extraction and Binding to Glass Powder", Analytical Biochemistry, 121:382-387						
47	Morrow, C., et al., 1989, "Structure of the Human Genomic Glutathione S-transferase-n gene", Gene, 75:3-11						
48	Oakeley, E., 1999, "DNA Methylation analysis: a review of current methodologies:, <i>Pharmacology & Therapeutics</i> , 84 :389-400						
49	Oakeley, E., et al., 1999, "Changing Functionality of Surface by Directed Self-Assembly Using Oligonucleotides – The Oligo-Tag", <i>BioTechniques</i> , 27 (<u>4</u>):752-760						
50	k, A., et al., 1996, "A modified and improved method of bisulphate based cytosine Methylation analysis", leic Acids Research, 24(24):5064-5066						
51	Paulin, R., et all., 1998, "Urea improves efficiency of bisulphate-mediated sequencing of 5'-methylcytosine in genomic DNA", <i>Nucleic Acids Research</i> , 26 (21):5009-5010						
52	Raizis, A., et al., 1995, "A Bisulfite Method of 5'-methylcytosine that minimizes template Degradation", Analytical Biochemistry, 226:161-166						
53	Volgelstein, B., et al., 1979, "Preparative and analytical purification of DNA from agarose", <i>Proc. Natl. Acad. Sci. USA</i> , 76(2):615-619						
54	Wang, R., et al., 1980, "Comparison of bisulfite modification of 5'-methylcytosine and deoxycytidine residues", <i>Nucleic Acids Research</i> , 8(20):4777-4790						
55	bisulphate-treated DNA", Nucleic Acids Research,, 25(21):4422-4426						
56							
57	Whelen, C., 1996, "The Role of Nucleic Acid Amplification and Dtection in the Clinical Microbiology Laboratory", Annu. Rev. Microbiol, 50:349-373						
58	Wu, D., et al., 1989, "The Ligation Amplification Reaction (LAR) – Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependent Ligation", Genomic, 4:560-569						
59	Zymo Research, , Instruction Leaflet of "EZ DNA Methylation Kit™"						
EXAMINER	DATE CONSIDERED						

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Docket Number (Optional) Application Number 21371-US 10/647,720 ÖRMATION DISCLOSURE CITATION Applicant(s) Christine Markert-Hahn and Dirk Block (se several sheets if necessary) Filing Date Group Art Unit NOV 1 4 2003 Unassigned August 25, 2003 U.S. PATENT DOCUMENTS EXAMINER FILING DATE DOCUMENT NUMBER NAME CLASS SUBCLASS DATE INITIAL IF APPROPRIATE 4,683,202 07/28/1987 Mullis 435 91 10/25/1985 2 5,130,238 07/14/1992 Malek, et al. 435 91 08/23/1989 3 5,137,806 08/11/1992 LeMaistre, et al. 435 6 12/11/1989 05/11/1993 Gelfand, et al. 6 08/06/1990 5,210,015 435 08/10/1993 Boom, et al. 435 91 07/01/1991 5,234,809 01/30/1996 01/05/1993 Gelfand, et al. 435 6 5,487,972 09/03/1996 6 07/19/1994 5,552,277 Nelson, et al. 435 91.2 01/21/1997 02/17/1995 5,595,890 Newton, et al. 435 5,639,611 06/17/1997 Wallace, et al. 435 6 11/09/1994 10 5,786,146 07/28/1998 Herman, et al. 435 6 06/03/1996 11 09/08/1998 6 04/25/1995 5,804,375 Gelfand, et al. 435 FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
	KEF						YES	NO
J_{μ}	12	EP 0 200 362 B1	01/20/1993	EP				
B	13	EP 0 201 184 B1	12/16/1992	EP				
1/	14	EP 0 389 063 B1	08/13/1997	EP				
V	15/	WO 90/01069	02/08/1990	PCT				
0	16	WO 90/06045	06/14/1990	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Abramson, R., et al., 1993, "Nucleic Acid Amplification Technologies", Curr Opinion Biotechnology, 4:41-47

Alderton, R., et al., 1992, "Magnetic Bead Purification of M13 DNA Sequencing Templates", Analytical Biochemisty, 201:166-169

EXAMINER DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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*EXAMINER			DOCUMENT NUMBER	DATE	-	NAME CLA		SUBCLASS	FILING DATE IF APPROPRIATE	
	19	6,17	74,670 B1	01/16/2001	Wittwer, et al.		435	6	6 01/16/200	
	20	6,33	31,393 B1	12/18/2001	Laird, et a.l		435	6	05/14/1999	
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	21	wo	92/02638	02/20/1992	PCT					
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e/	25	wo	0 00/32762	06/08/2000	PCT					
			OTHER DOCUME	NTS (Includin	g Author	, Title, Date, Pertinent i	Pages, Etc.)		
		Barany, F., 1991, "Review: The Ligase Chain Reaction in a PCR World", PCR Methods and Applications, 1(1):5-16								
	Barany, F., 1991, "Genetic Disease Detection and DNA amplification using cloned thermostable ligase", <i>Proc. Natl. Acad. Sci. USA</i> , 88:189-193									
EXAMINER					DATE CONSIDERED					
			ference considered, whethe by of this form with next con			ance with MPEP 609; Draw	line through c	itation if not in co	onformance	and not

Form PTO-A820 (also form PTO-1449)

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